

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WISCONSIN

AMERITOX, LTD., and
MARSHFIELD CLINIC, INC.,

Plaintiffs,

v.

MILLENNIUM HEALTH, LLC,

Defendant.

OPINION AND ORDER

13-cv-832-wmc

Defendant Millennium Health, LLC moved in limine for an order excluding any evidence of willful infringement on the basis that Ameritox cannot show by clear and convincing evidence that Millennium “acted despite an objectively high likelihood that its actions constituted infringement of a valid patent.” *In re Seagate Technology, LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007) (*en banc*). The court declined to decide the issue on the eve of trial, opting instead to hear the evidence submitted in the invalidity phase before deciding the objective prong of the willful infringement claim. (4/3/15 Op. & Order (dkt. #380) 50.)

Having now had the benefit of hearing that evidence, as well as additional arguments and proffers by counsel for the parties, the court finds that Millennium’s invalidity defense under § 103 is objectively reasonable. In particular, for reasons explained below, while the jury had sufficient evidence to find that the combination of the elements of claims 1, 2, 4-7, 10, and 16-18, of the ‘608 patent were not obvious, the court finds this was a “substantial question” and, therefore, plaintiffs have not met their burden of establishing that Millennium *willfully* infringed the patent. *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, 776 F.3d 837, 844 (Fed. Cir. 2015) (“*Bard II*”).

The court further finds a substantial question with respect to Millennium's defense under § 101, although this a closer question given the treatment of patent eligibility at the time of infringement.¹

Despite this ruling, the court has also decided to permit the jury to resolve the so-called "subjective" prong of the willfulness standard. This is being done *solely* to avoid the necessity of an additional trial should the Federal Circuit disagree with this court's conclusion as to the objective prong, now that the jury has heard substantially, if not all, of the evidence necessary to reach this fact question. This opinion, therefore, further elaborates on the limits of admissible evidence and argument with respect to this question.

OPINION

I. Objective Test

A. § 103 Defense

As Millennium argued to the jury, it believes that the '608 patent is invalid as obvious under 35 U.S.C. § 103. As an initial matter, the court may consider arguments developed during the course of litigation. *See Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 769 F.3d 1371, 1382 (Fed. Cir. 2014) ("The court properly considered the totality of the record evidence, including the obviousness defense that Pulse developed during the litigation, to determine whether there was an objectively-defined risk of infringement of a valid

¹ For the reasons previously provided in the court's previous decisions, the court continues to believe that defendant's claims construction / noninfringement defense was not objectively reasonable.

patent.” (internal citations and quotations omitted)). The court finds all of the essential elements were present in the prior art, or at least that such a belief was objectively reasonable. The court also finds objectively reasonable the argument that one skilled in the art would make the step of combining these elements using Kell, and substituting creatinine for specific weight. *See Bayer Schering Pharma AG v. Barr Labs., Inc.*, 575 F.3d 1341, 1348 (Fed. Cir. 2009) (affirming district court’s finding that the patent was obvious because it would have been “obvious to try” the invention).

In no way does this finding upend the jury’s rejection of defendant’s obviousness defense -- the jury had a sound basis for finding that Larson should have been given credit for taking the additional step of identifying a meaningful comparison between an individual’s metabolic urine concentration to a normative data set, notwithstanding persuasive expert testimony to the contrary. The court simply finds that defendant raised a “substantial question” of obviousness to warrant dismissal of plaintiffs’ willful infringement claim on the objective prong. *See Bard II*, 776 F.3d at 844; *see also Spine Solutions, Inc. v. Medtronic Sofamor Danek USA, Inc.*, 620 F.3d 1305, 1319 (Fed. Cir. 2010) (“Although we hold that the record contains substantial evidence to support the jury’s implicit finding that one of skill in the art would not have found the combination obvious, Medtronic was not objectively reckless in relying on this defense.”).

B. § 101 Defense

Given the developing law with respect to § 101, the court also finds a substantial question exists as to how the Supreme Court and Federal Circuit will ultimately land on

the patenting of the advancement of combining basic and well-known scientific steps to achieve marginal advance, although highly marketable, in an existing medical product.² First, as to 35 U.S.C. § 101, the Supreme Court's holding that the patent considered in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012), was invalid under § 101, is supportive of plaintiffs' position, at least on a facial level. There is substantial evidence that each element (a) through (f) of the claims in the '680 patent were known. Only when one looks more closely at the combination of element (e) and element (f) -- and whether there were disputed facts as to whether that combination existed -- did the court find the present case distinct from *Mayo*, at least in the context of summary judgment.³ Given this finer line of distinction between *Mayo* and the instant case, plaintiffs face a difficult hurdle and cannot discharge their burden of proving by clear and convincing evidence that the objective prong is met. Second, instead of acting like the coarse "filter" it once was, § 101 is considered a strong shield in defending against patent infringement claims, particularly in the post-*Alice* landscape. *Alice Corp. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014). Indeed, § 101 now arguably imposes a "higher

² At least one district court has questioned whether developments in the law may be considered in determining the objective prong of a willful infringement claim. See *Smartflash LLC v. Apple Inc.*, Nos. 6:13cv447-JRG-KNM, 6:13cv448-JRG-KNM, 2015 WL 661276, at *5 (E.D. Tex. Feb. 13, 2015). Even if such developments cannot be considered, *Mayo* is consistent with the law as expressed in *Parker v. Flook*, 437 U.S. 584, 599 (1978), and *Diamond v. Diehr*, 450 U.S. 175, 185 (1981). In *Mayo*, the Supreme Court essentially reconciled these cases and applied their principals to the facts of that case.

³ This distinction was supported by Federal Circuit cases that were issued in late 2014. See *In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755 (Fed. Cir. 2014); *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245 (Fed. Cir. 2014).

bar,” invalidating numerous patents in district courts and *inter partes* proceedings before the Patent Office. *See Cal. Inst. of Tech. v. Hughes Commc’n*, No. 2:13-cv-07245-MRPHEM, 2014 WL 5661290, at *2 (C.D. Cal. Nov. 3, 2014). Because of this reinvigoration of the § 101 defense, and the developing case law that will no doubt receive greater elaboration and guidance by the Federal Circuit, if not the United States Supreme Court, Millennium’s reliance on this defense is objectively reasonable.

II. Subjective Prong

A. Standard

As briefly described in the introduction, the Federal Circuit has articulated a two-prong test for willful infringement, which requires the patent holder to show by clear and convincing evidence that: (1) “the infringer acted despite an objectively high likelihood that its actions constituted infringement;” and (2) “that this objectively-defined risk . . . was either known or so obvious that it should have been known to the accused infringer.” *In re Seagate Tech., LLC*, 497 F.3d 1360 (Fed. Cir. 2007) (*en banc*). In *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs.*, 682 F.3d 1003 (Fed. Cir. 2012) (“*Bard I*”), the Federal Circuit determined that the first prong of *Seagate* is an issue for the court to determine. “[T]he ultimate legal question of whether a reasonable person would have considered there to be a high likelihood of infringement of a valid patent should always be decided as a matter of law by the court.” *Id.* at 1008.⁴

⁴ The *Bard I* court left open the possibility of the jury determining factual issues that underpin the objective prong of the test, but the court has the discretion as to whether to pose specific interrogatories to the jury. *Bard I*, 682 F.3d at 1008 (“In considering the

That much is clear. What remains uncertain -- at least in a case like the one before this court -- is what is left for the jury to decide assuming a court finds the defendant acted despite an objectively high likelihood that it was infringing.⁵ Returning to the Federal Circuit's language in *Seagate*, which is reiterated by the court in *Bard I*, the jury must decide whether the objectively high risk of infringing a valid patent was known or should have been known to Millennium. This finding necessarily assumes knowledge of the patent -- and Millennium concedes that it knew of the '608 patent before introducing the infringing RADAR Report product. (4/7/15 Hearing Tr. (dkt. #385) 152 (acknowledge that Millennium is "prepared to stipulation . . . that we were aware of the patent"). The pertinent question then is what *else* would need to be shown for the jury to find knowledge of risk of infringement of a valid patent.

objective prong of *Seagate*, the judge *may* when the defense is a question of fact or a mixed question of law and fact allow the jury to determine the underlying facts relevant to the defense in the first instance, for example, the questions of anticipation or obviousness.").

⁵ It appears that the Federal Circuit is also struggling with this issue. In a recent case, the court has hinted that the strength of the objective finding could diminish the need to consider a separate subjective finding. See *Aqua Shield v. Inter Pool Cover Team*, 774 F.3d 766, 774 (Fed. Cir. 2014) ("[O]bjective baselessness of an infringer's defenses, assessed on the litigation record, may have a strong bearing on whether the 'objectively-defined risk' of infringement 'was either known or so obvious that it should have been known to the accused infringer.'" (quoting *Seagate*, 497 F.3d at 1371)). Even more recently, some members of the Federal Circuit urged an *en banc* review of several issues surrounding willful infringement claim, including the "evidentiary wall" between the two prongs of the willful infringement claim and whether there is any role for the jury in light of the statutory language that "*the court* is the entity to decide whether the remedy is appropriate." *Halo Electronics, Inc. v. Pulse Electronics, Inc.*, Nos. 2013-1472, 2013-1656, 2015 WL 1283767, at *4-6 (Fed. Cir. Mar. 23, 2015) (O'Malley, J., dissenting from denial of petition for rehearing en banc).

B. Waiver Claim

As an initial matter, plaintiffs have argued that Millennium may not rely on its obviousness or anticipation defenses to plaintiffs' willful infringement claim in light of Millennium's discovery response to one of plaintiffs' specific, contention interrogatories in this case. Specifically, Millennium was asked to "[s]tate and describe in detail all factual and legal bases for Your contention that Millennium has not willfully infringed the '680 patent or the '895 patent." (Pls.' Pre-Trial Submission in Light of Final Pre-Trial Conf. (dkt. #394) 2; Br. In Supp. of Mot. to Exclude Bero, Ex. D (dkt. #275-4) No. 25.) In response, Millennium principally directed plaintiffs to "its positions with respect to non-infringement and invalidity in its motion for summary judgment." (Br. In Supp. of Mot. to Exclude Bero, Ex. D (dkt. #275-4) 11.) Relying on this response alone, plaintiffs argue that since Millennium did not raise obviousness or infringement in its motion for summary judgment, it should be precluded from raising either as a defense to willfulness.

Given that the focus of Millennium's summary judgment motion was validity under § 101, many, if not all, of which included essential elements of its § 102 and § 103 defenses, and that Millennium had preserved both defenses for trial, the court finds plaintiffs' wholly unpersuasive. There can be no dispute that plaintiffs were aware of Millennium's intention to assert its obviousness and anticipation claims. Indeed, plaintiffs prevailed on both at trial. Therefore, there is no prejudice to plaintiffs by allowing Millennium to rely on its beliefs about the invalidity of the patent under § 102

and § 103 grounds in defending against the subjective prong of plaintiffs' willfulness claim.

C. Merits

While there is little case law post-*Bard I* on the subjective prong of the test, it appears that those opinions focus on whether the infringer *knew* of the patent.⁶ Most notably, the Federal Circuit in *SSL Services, LLC v. Citrix Systems, Inc.*, 769 F.3d 1073 (Fed. Cir. 2014), affirmed the district court's finding of willful infringement in part because there was substantial evidence to support the jury's finding that the infringer "knew of the objectively high risk that its products infringed the asserted claims of the . . . patent." *Id.* at 1092. In so finding, the court exclusively relied on evidence of the infringer's knowledge of the patent. *Id.* Moreover, the court affirmed the district court's exclusion of fact testimony from the defendant's chief engineer that: "(1) Citrix believed in good faith that its products were non-infringing; and (2) that reexamination proceedings had been initiated at the PTO." *Id.* In so holding, the court agreed with the district court's determination that the chief engineer's "personal beliefs regarding non-

⁶ See, e.g., *Calico Brand, Inc. v. Ameritek Imports, Inc.*, 527 Fed. Appx. 987, 993-94 (Fed. Cir. 2013) (unpublished) (affirming district court's reversing of jury's finding of willful infringement, in part, because there was "no showing that [defendant] had *knowledge* of Calico's patents at the time it was selling the infringing Ameritek lighters before October 22, 2004" (emphasis added)); *RLIS, Inc. v. Cerner Corp.*, No. 3:12-CV-209, 2014 WL 7205434, at *1 (S.D. Tex. Dec. 17, 2014) ("Based on the evidence in the record, the jury could reasonably find that Cerner *knew* about both of the RLIS patents." (emphasis added)); cf. *Apple, Inc. v. Samsung Elecs. Co., Ltd.*, 920 F. Supp. 2d 1116, 1131 (N.D. Cal. 2013) (affirming jury's finding on the subjective prong where the court found that defendant's belief that the patent was limited in scope was objectively reasonable, and therefore "Apple's evidence thus does little to establish that Samsung knew or should have known it was infringing").

infringement, the fact that they were beliefs formed by a lay person without the benefit of the court's claim construction determinations *rendered them of little probative value and potentially prejudicial.*" *Id.* (emphasis added). As for the PTO reexamination, the court also found them properly excluded under Rule 403 because of "this court's precedent . . . of the limited value of actions by the PTO to establish a good faith belief of invalidity." *Id.* at 1092-93 (internal citation and quotation marks omitted).

In its supplemental submission in support of its argument that the "subjective prong hinges on the fact finder's assessments of the credibility of witnesses," Millennium cites three cases. (Def.'s Submission Regarding Willfulness (dkt. #296) 2.) In the first case, *LG Electronics U.S.A., Inc. v. Whirlpool Corp.*, 798 F. Supp. 2d 541, 557 (D. Del. 2001), the district court appears to have charged the jury with *both* prongs of the *Seagate* test -- the case preceded *Bard* -- and the court rejected plaintiff's challenge to the jury's finding of non-willfulness on the basis that the evidence presented by the defendant supported the jury's finding that the plaintiff failed to prove the defendant's objective recklessness. As an initial matter, this blanket statement about the importance of the jury assessing credibility could concern a jury's assessment of whether the defendant knew or should have known about the patent -- the court did not describe specifically what is covered by the subjective prong. Moreover, regardless of this blanket statement, the court ultimately affirmed the jury's verdict based on their finding as to the objective prong of the test.

Next, Millennium cites an unpublished Federal Circuit case from 2004, which predates both *Seagate* and *Bard*, in which the court reversed the district court's grant of

judgment as a matter of law, finding substantial evidence to support the jury's finding of infringement and willful infringement. *Pordy v. Land O'Lakes, Inc.*, 97 F. App'x 921, 927 (Fed. Cir. 2004). The court's discussion, however, appears limited to the jury's finding of infringement, and does not touch on the willful infringement claim specifically. *Id.* In other words, there is no indication that the court considered what evidence the jury should review in evaluating the subjective prong of the test, especially since the case precedes the articulation of a subjective prong and how it is distinguished from the court's role under the objective prong.

Finally, Millennium cites a 2009 Federal Circuit case in which the court quotes language from an earlier case, but explicitly did *not* consider a willful infringement claim, since none was alleged. *Revolution Eyewear, Inc. v. Aspex Eyewear, Inc.*, 563 F.3d 1358 (Fed. Cir. 2009). The court in *Revolution Eyewear* cited *National Presto Industries, Inc. v. West Bend Co.*, 76 F.3d 1185 (Fed. Cir. 1996), but similarly this case does not assist the court in determining the jury's role under the subjective prong given that the court in *National Presto* simply reiterated that willful infringement is a question of fact -- a position that was wholly upended in *Bard*. *Id.* at 1192-93. For example, the court instructed in that case that the jury should consider the reasonableness of the infringer's actions, while *Bard* held that the reasonableness of the defendant's actions is for the court to determine. *Bard*, 682 F.3d at 1008.

At the final pretrial conference, Millennium identified three areas of evidence it plans to offer at trial to rebut the subjective prong of the willful infringement claim.⁷ *First*, Millennium seeks to introduce evidence of “[t]he subjective state of mind of Millennium in connection with how the patent distinguished over prior art and whether it was therefore invalid.” (4/7/15 Hearing Tr. (dkt. #385) 153.) This is Millennium’s strongest argument, since the jury will have decided its invalidity defenses. Still, what does it mean for the jury to find that Millennium believed in good faith that the patent was invalid in light of prior art, if the court had determined (as it ordinarily must do for the subjective question to be given to the jury) that Millennium’s belief was not objectively reasonable (e.g., whether Millennium had a “reasonable defense to a charge of infringement,” *Bard*, 682 F.3d at 1005-06)? In particular, the introduction of this evidence to the jury has at least the *potential* of subsuming the court’s role under the objective prong of the test.

Second, Millennium seeks to introduce evidence of “why Millennium pursued its two reexaminations before the Patent Office, two times resulting in determinations that there was a significant question going to patentability.” (4/7/15 Hearing Tr. (dkt. #385) 153.) This evidence seems properly excluded under Rule 403 in light of the Federal Circuit’s reasoning in *SSL*. 769 F.3d at 1092; *see also WBIP, LLC v. Kohler Co.*, No. 11–10374–NMG, 2014 WL 585854, at *6 (D. Mass. Feb. 12, 2014) (“[T]he Federal Circuit has held that the occurrence of a reexamination is not probative on the issues of validity

⁷ These same areas were reiterated in Millennium’s supplemental submission. (Def.’s Suppl. Submission of Willfulness (dkt. #296) 4.

or willfulness.” (citing *Hoechst Celanese Corp. v. BP Chems. Ltd.*, 78 F.3d 1575, 1584 (Fed. Cir. 1996))). Moreover, Millennium’s reexamination efforts reflect *post hoc* activities, which do not reflect its state of mind at the time it began infringing Ameritox’s patent.⁸

Third, Millennium seeks to introduce evidence of “the subjective state of the mind of Millennium in regard to claim construction informed by how Ameritox characterized the patent and tied it to both its dose-specific determinations and to the Marshfield compliance database, and issues regarding Ameritox’s argument that there was deliberate copying which requires, under Federal Circuit case law, an intent to replicate a specific product.” (4/7/15 Hearing Tr. (dkt. #385) 153.) This evidence also appears properly excluded under *SSL*. 769 F.3d at 1092-93 (affirming exclusion of defendant’s chief engineer that he believed in good faith that defendant was not infringing). Millennium’s belief about claims construction would confuse the jury in light of the court’s presumed finding that Millennium’s claims construction (and related belief that it was not infringing) was not objectively reasonable. Indeed, as far as the court can tell, Millennium appears to be arguing that its view of the patent was tied to Ameritox’s statements about *a* possible embodiment of the patent. Moreover, Millennium believed that the statements Ameritox made about its product were false. This circuitous argument, ushered in by lay persons, concerning claims construction which -- if anything is clear -- is an issue for the court would be unduly confusing and therefore prejudicial to plaintiff under Federal Rule of Evidence 403. Moreover, Millennium knew, or at least *should* have known, that any statements Ameritox was making to the market about its

⁸ See *supra* discussion pp.13-14.

product or even about the '680 patent has *nothing* to do with the scope or validity of the patent itself, and was certainly not something it could rely on in forming an opinion about its validity or possible infringement of that patent. *See Zenith Labs. v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 1423 (Fed. Cir. 1994) (“As we have repeatedly said, it is error for a court to compare in its infringement analysis the accused product or process with the patentee’s commercial embodiment or other version of the product or process; the only proper comparison is with the claims of the patent.”); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 985–86 (Fed. Cir. 1995) (recognizing that an inventor may not understand the scope of the claims). Finally, the court finds for reasons also amply explained that its position on infringement was *so* objectively unreasonable that it need not go to the jury, even on a subjective basis. *See Aqua Shield*, 774 F.3d at 774.

The parties’ submissions also bring to light an issue about the relevant timeframe for the jury’s consideration of the subjective prong. Millennium acknowledges in its initial supplemental submission that “[d]ocuments that were not in an infringer’s possession at the time of any infringement are likewise not relevant to subjective willfulness but remain relevant to the objective inquiry.” (Def.’s Suppl. Submission on Willfulness (dkt. #396) 2.) In its response to plaintiffs’ submission, however, Millennium appears to balk at being limited to evidence of what it knew before June 2, 2011, the first date of infringement, arguing instead that “Millennium’s information and state of mind as it changed over the course of time therefore becomes relevant.” (Def.’s Resp. to Pl.’s Willfulness Suppl. Submission (dkt. #401) 5.) The cases cited by Millennium for that proposition, however, do not provide the support Millenniums

claims. First, in *Vulcan Engineering Co., Inc. v. Fata Aluminum, Inc.*, 278 F.3d 1366 (Fed. Cir. 2002), the Federal Circuit affirmed the district court's finding that the defendant's infringement was not willful in part based on efforts to seek advice of counsel after receiving a notice of possible infringement. *Id.* at 1378-79.⁹ While these actions post-dated defendant's knowledge of the patent, the court noted that defendant's actions occurred "at a time when its bid had been accepted but no other infringing activity was shown." *Id.* at 1379. In other words, the relevant timeframe was still what was known at the time defendant began infringing. Second, in *Paper Machine Co. v. Magna-Graphics Corp.*, 745 F.2d 11 (Fed. Cir. 1984), the Federal Circuit remanded for the district court to consider whether the defendant's continued infringement after the district court issued an injunction against infringement constituted willful infringement. *Id.* at 20-21. Here, there is no such intervening act -- or at least Millennium has failed to identify any -- which would prompt consideration of whether willful infringement began at a later time than the date of infringement (e.g., the date on which defendant acquired knowledge of the patent or some other information that would have triggered its awareness of the risk of infringement). *See, e.g., Calico Brand, Inc. v. Ameritek Imports, Inc.*, 527 Fed. Appx. 987, 993-94 (Fed. Cir. 2013) (considering evidence after the start of infringement when the defendant learned of its potential liability and demanded assurances from the plaintiff that it was not infringing).

⁹ Millennium incorrectly describes this case in a parenthetical as "uphold[ing a] jury finding of no willfulness." (Def.'s Resp. to Pls.' Suppl. Submission on Willfulness (dkt. #401) 5.) *See Vulcan Eng'g*, 278 F.3d at 1370 (noting that judgment was entered after a bench trial).

So, where does this leave us? The law is clear that the court has the role of determining whether defendant's actions were reasonable. *Bard I*, 682 F.3d at 1008 (“[T]he judge remains the final arbiter of whether the defense was reasonable.”). In light of the court's determinations as to the scope of the subjective prong and what evidence would be appropriate for the jury to consider, the court will allow the jury to decide whether Millennium knew or should have known that the '608 patent was valid. The court will circulate a willfulness jury instruction and special verdict form consistent with this opinion. In addition, the court requests that the parties each submit a proffer of the additional evidence, if any, they seek to introduce in this third phase of the trial by 5:00 p.m. on Sunday, April 19, 2015.

Entered this 17th day of April, 2015.

BY THE COURT:

/s/

WILLIAM M. CONLEY
District Judge